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6 IN THE UNITED STATES DISTRICT COURT
7 FOR THE MIDDLE DISTRICT OF GEORGIA
8 COLUMBUS DIVISION

9 IN RE MENTOR CORP. OB TAPE
10 TRANSOBTURATOR SLING PRODUCTS
11 LIABILITY LITIGATION

MDL CASE NO. 2004

Individual Case No. 4:11-cv-05065 (Morey)

Plaintiff Irene Morey's First Amended
Complaint

12
13 **COMPLAINT**

14 The Complaint and Demand for Jury Trial of Irene Morey, as Plaintiff (hereinafter the
15 "Plaintiff") shows as follows:

16 **JURISDICTION AND PARTIES**

17 1. At all times relevant herein, Plaintiff was a resident of the State of Washington.

18 2. At all times relevant herein, Defendant Mentor Corporation (hereinafter
19 "Defendant" or "Defendant Mentor") was a Minnesota corporation with its principal place of
20 business in California. All acts and omissions of Defendant Mentor as described herein were
21 done by its agents, servants, employees, and/or owners, acting in the course of and scope of their
22 respective agencies, services, employments and/or ownership.

23 3. Plaintiff is seeking damages in excess of \$75,000.00. Subject matter jurisdiction
24 is proper pursuant to 28 U.S.C. Section 1332.
25
26

1 4. A substantial part of the events and omissions giving rise to Plaintiff's cause of
2 action occurred in Minnesota. Defendant Mentor was incorporated in Minnesota, performed
3 research and development of the product in Minnesota, has significant contacts in Minnesota,
4 and has earned substantial compensation and profits from sales of its products in this District.
5 Pursuant to 28 U.S.C. Section 1391(a) venue is proper in the District of Minnesota.
6

7 **FACTUAL BACKGROUND**

8 5. At all times relevant herein, Defendant Mentor was engaged in the business of
9 designing, manufacturing, marketing, packaging, labeling, and selling medical devices, including
10 a medical device known as "ObTape," a transobturator vaginal sling implanted suburethrally to
11 treat certain women like Plaintiff for stress urinary incontinence.
12

13 6. Defendant brought ObTape to market in the United States in 2003 without
14 adequate pre-market testing as to the safety and efficacy of said device (the only pre-market
15 "testing" that Defendant performed on the ObTape was animal testing on three rabbits). Even
16 the limited pre-market testing that Defendant did perform revealed that the ObTape caused
17 adverse tissue reaction in rabbits. After the ObTape was brought to market, Defendant
18 performed no additional safety or efficacy testing in human vaginal tissues regarding said device.
19

20 7. The material of which the ObTape sling was constructed (non-woven,
21 microporous, inelastic polypropylene mesh) was inappropriate for use in the vaginal area.
22

23 8. The pore size of the polypropylene mesh sling was insufficient to allow for proper
24 physiological reaction of the body to the device, in that the pore size was too small to permit in-
25 growth of small blood vessels, cells that make collagen, and white blood cells.
26

1 9. The inappropriate material and inadequate pore size in the Mentor ObTape
2 vaginal sling created a propensity for infection and/or abscess when placed in the vaginal area,
3 which consequently resulted in an unreasonably high rate of infection, abscesses, erosion and
4 extrusion.

5
6 10. The foreseeable risks of harm posed by the design of the Mentor ObTape vaginal
7 sling could have been reduced and/or avoided by the adoption of a reasonable alternative design
8 by the Defendant, and Defendant's unreasonable failure to adopt a safer alternative design
9 rendered the Mentor ObTape vaginal sling unreasonably hazardous.

10 11. Certain of Defendant's design and manufacturing specifications for the Mentor
11 ObTape vaginal sling product called for a minimum pore size of 50 microns in order to promote
12 proper tissue in-growth.

13
14 12. When the Mentor ObTape vaginal sling left the Defendant's possession or control,
15 it deviated in a material way from Defendant's design and manufacturing specifications in that
16 many of the pores in the ObTape sling were smaller than 50 microns, which prevented proper
17 integration of the vaginal sling and impaired necessary tissue in-growth, thereby increasing the
18 likelihood of serious infection, abscesses, vaginal erosion and extrusion.

19
20 13. Defendant knew or should have known of the manufacturing defects and the risk
21 of serious bodily injury associated with the small pore size of the Mentor ObTape vaginal sling,
22 but unreasonably or with deliberate disregard for or indifference to the safety of the women using
23 its product failed to take action with respect to said defects.

24
25 14. Defendant negligently or with deliberate disregard for or indifference to the safety
26 of the women using its product failed to provide such warning or instruction that a manufacturer

1 exercising reasonable care would have provided to physicians who implanted the Mentor ObTape
2 vaginal sling, or those women who had been implanted with Mentor ObTape vaginal sling,
3 concerning the following risks, of which Defendant had actual or constructive knowledge at the
4 time the ObTape vaginal sling left Defendant's control: The high failure rate of the ObTape
5 product; the high rate of infections and abscesses caused by the product; the high rate of vaginal
6 erosions and extrusions caused by the product; ObTape's susceptibility to vaginal erosion, and
7 the consequential necessity to remove the entire sling from the patient's body in the event of an
8 erosion; and that the product was unsafe for its intended use of treating female stress
9 incontinence.
10

11
12 15. Before Plaintiff suffered the injuries complained of herein, Defendant was on
13 notice of numerous bodily injuries caused by ObTape, and based thereon, Defendant knew or
14 should have known that the ObTape caused an unreasonably high rate of vaginal erosion,
15 infection, extrusion, perforation and/or abscess in women implanted with said device, but
16 unreasonably or with deliberate disregard for or indifference to the safety of the women using its
17 product failed to take action with respect to said adverse consequences.
18

19 16. Before Plaintiff suffered the injuries complained of herein, Defendant, despite
20 strong and mounting evidence of a high rate of serious injuries caused by its product, callously
21 prioritized sale of its left-over inventory of ObTape and a smooth transition to ObTape's
22 successor macroporous product Aris over warning physicians of the mounting evidence that
23 ObTape was a dangerous product.
24

25 17. Even though Defendant knew or should have known much earlier than March of
26 2006 that the ObTape created a foreseeable, unreasonable risk of harm to those women who were

1 implanted with said device, Defendant unreasonably or with deliberate disregard for or
2 indifference to the safety of the women using its product failed to stop marketing the ObTape in
3 United States until in or around March of 2006, and not until after Defendant had sold tens of
4 thousands of these devices in the United States alone, including the ObTape vaginal sling
5 ultimately implanted in Plaintiff.
6

7 18. Even after Defendant ceased marketing the ObTape device in the United States in
8 or around March 2006 because of the numerous injuries caused by the product, Defendant
9 unreasonably failed to provide adequate warnings or information to physicians who implanted
10 the device, or to women who were implanted with the device, failed to inform them that the
11 ObTape caused an unreasonably high rate of vaginal erosion, infection, extrusion, perforation
12 and/or abscess.
13

14 19. Plaintiff underwent a surgical procedure wherein she was implanted with Mentor
15 ObTape vaginal sling on December 29, 2004.

16 20. On June 10, 2005, Plaintiff was diagnosed with vaginitis and learned for the first
17 time that she had been injured by ObTape. She was subsequently diagnosed with extrusion of
18 ObTape, and on June 29, 2005, surgery requiring hospitalization was performed to partially
19 remove the ObTape device.
20

21 21. As a direct and proximate result of Mentor's negligence or deliberate disregard for
22 or indifference to the safety of the women using its product with respect to the design,
23 manufacture, warnings, and post-marketing follow-up of the Mentor ObTape vaginal sling and
24 other misconduct of Defendant as described in this Complaint, Plaintiff suffered serious bodily
25 injury, experienced significant mental and physical pain and suffering, has required surgery, has
26

1 sustained permanent injury and other damages, has expended and will continue to expend large
2 sums of money for medical care and treatment, has suffered economic loss and/or lost income,
3 and has otherwise been physically, emotionally and economically injured.

4
5 **COUNT I-NEGLIGENCE**

6 22. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set
7 forth herein.

8 23. Defendant owed a duty to Plaintiff to exercise ordinary and reasonable care in
9 designing, manufacturing, testing, marketing, labeling, packaging, selling and/or distributing the
10 ObTape vaginal sling, and to exercise ordinary and reasonable care in providing adequate
11 warnings and instructions to Plaintiff and to her physicians regarding the Mentor ObTape vaginal
12 sling.

13
14 24. Defendant failed to exercise ordinary and reasonable care in designing,
15 manufacturing, testing, marketing, labeling, packaging, selling and/or distributing the Mentor
16 ObTape vaginal sling, and Defendant negligently failed to provide adequate warnings and
17 instructions to Plaintiff and to her physicians regarding the Mentor ObTape vaginal sling.

18
19 25. Defendant breached their duty of reasonable care to Plaintiff by failing to
20 promptly and adequately notify Plaintiff, Plaintiff's doctors, the medical community, and the
21 public at the earliest possible date of known defects in the Mentor ObTape vaginal sling.

22 26. Defendant breached its duty of reasonable care to Plaintiff by failing to exercise
23 due care under the circumstances.

24 27. As a direct and proximate result of the Defendant's negligence, Plaintiff suffered
25 serious and permanent bodily injuries, experienced significant mental and physical pain and
26

1 suffering, has required surgery and hospitalization, and has expended and will continue to expend
2 large sums of money for medical care and treatment, has suffered and will continue to suffer
3 economic loss and/or lost income, and has otherwise been physically, emotionally and
4 economically injured.

5
6 **COUNT II-PUNITIVE DAMAGES**

7 28. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set
8 forth herein.

9 29. Defendant acted with deliberate disregard for or indifference to the high
10 probability that Plaintiff and other women implanted with ObTape would suffer unnecessary
11 serious injury as a result of using their product.

12
13 **PRAYER FOR RELIEF**

14 WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

- 15 1. Economic and non-economic damages in an amount in excess of \$75,000 as provided
16 by law and to be supported by the evidence at trial;
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18 2. For compensatory damages according to proof;
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20 3. For punitive damages;
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22 4. For an award of fees and costs;
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24 5. For prejudgment interest and the costs of suit; and
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26 6. For such other and further relief as this Court may deem just and proper.

1 **DEMAND FOR JURY TRIAL**

2 Plaintiff hereby demands a trial by jury as to all claims in this action.

3 DATED this 24th day of January, 2013.

4
5 METZ LAW GROUP, PLLC

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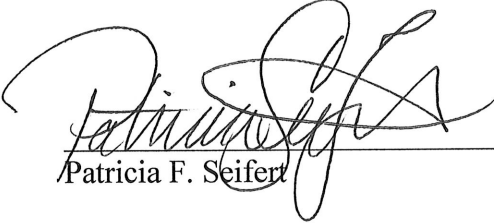
CERTIFICATE OF SERVICE

I, Patricia F. Seifert, hereby declare that a copy of the foregoing document was served upon the following counsel of record on the 24th day of January, 2013.

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DATED THIS 24th day of January, 2013.



Patricia F. Seifert